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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,525	02/27/2004	Richard James Cawthray	9192ML	7746

27752 7590 10/17/2007

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EXAMINER	
ROBERTS, LEZAH	
ART UNIT	**PAPER NUMBER**
1614	

MAIL DATE	DELIVERY MODE
10/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/789,525	CAWTHRAY ET AL.	
	Examiner	Art Unit	
	Lezah W. Roberts	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *A-B*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Restriction Requirement

Applicant's election with traverse of Group I in the reply filed on August 2, 2007 is acknowledged. The traversal is on the ground(s) that the claims are directly or indirectly dependent on claim 1. This is not found persuasive because the kit may be used as a storage device and not as a memory aid as recited in method claim 24.

The requirement is still deemed proper and is therefore made FINAL.

Claims

Claim Rejections - 35 USC § 112 – Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recite the limitation of a pharmaceutical active and a nutrient but do not give any indication of what is encompassed by the broad terms pharmaceutical active and nutrient.

The appearance of mere indistinct words in a specification or a claim (here the word "pharmaceutical active" and "nutrient"), even an original claim, does not

necessarily satisfy the written description requirement. The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. Univ. of Rochester v. G.D. Searle, 69 USPQ2d 1886, 1892 (CAFC 2004). A description of what a material does, rather than of what it is, usually does not suffice to provide an adequate written description of the invention. Univ. of Cal. v. Eli Lilly, 119 F.3d 1559, 1568 (Fed. Cir. 1997). The disclosure only describes the pharmaceutical as bisphosphonates and the nutrient as calcium containing compounds. These compounds are related to a method of treating osteoporosis. The bisphosphonates may also be used for cancer, Paget's disease and other bone resorptive disorders. The bisphosphonates include risedronate, alendronate, pamidronate, tiludronate, cimadronate, ibandronate, and zoledronate. The reference does not disclose other pharmaceutical agents that may be included in the kits or give any indication of what other types of pharmaceutical agents may be used in the kits. In regards to the nutrient, the specification discloses that nutrient means any nutritional or dietary supplement including but not limited to vitamins, minerals, amino acids, herbs or other botanicals, or concentrates, metabolites, constituents, extracts, or combinations of the same. The preferred nutrients are calcium and/or vitamin D. The specification does not describe what other compounds are encompassed by the listed class of compounds above. The claims as written encompass more than pharmaceuticals and nutrients relating to the above mentioned disease.

Claim Rejections - 35 USC § 112 - Indefiniteness

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 2 recites the limitation "the memory" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103 – Obviousness

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strein (US 5,366,965).

Strein discloses a regimen for treatment of osteoporosis comprising administering to a patient a drug for only one day of an intermittent period wherein there are at least two periods lasting 2 to 14 days (col. 3, line 62 to col. 4, line 20). This encompasses the frequency of administering the drug as recited in the instant claims. The drug may be any suitable bone resorption inhibiting polyphosphonate including alendronate, pamidronate, tiludronate, and risedronate (col. 4, lines 35-60), encompassing claim 4. A vitamin may be administered during a rest period, which is a period of time during which the patient is not given a bone resorption inhibiting polyphosphonate, nor is the patient subjected to a bone cell-activating amount of a bone cell activating compound or other conditions, which would result in significant activation or inhibition of new bone remodeling units. The vitamins include calcium and vitamin D (col. 5, lines 44-65), encompassing claim 3. The present invention further relates to a kit for conveniently and effectively implementing methods of treatment in accordance with the disclosed invention. Such a kit preferably includes a number of unit dosages, which

makes convenient the correct administration of the dosages in a treatment regime according to this invention, as disclosed above. For example, in a treatment regime comprising cycles each including inhibiting periods which consist of 3 intermittent periods, each seven days long, it would be suitable to group dosages in sets of three, one for each of the three intermittent periods during each inhibiting period, and to indicate beside each dosage the date on which that dosage should be administered. Alternatively or additionally, it would be suitable to include a number of placebo dosages (preferably in a form similar to the polyphosphonate dosages and comprising an inert material or, e.g., a nutrient supplement) equal to the number of days for which polyphosphonate is not administered. One specific embodiment of the invention comprises a card having the components of the treatment regimen in the order of their intended use. An example of such a card is a "blister pack". As is well known, it is desirable to provide a memory aid on the card, e.g., in the form of numbers adjacent to the dosages, which numbers correspond to the days in the regimen in which the dosages should be administered, e.g., the date (col. 6, lines 25-65). The reference differs from the instant claims insofar as it does not disclose the pharmaceutical and the nutrients are arranged horizontally or vertically or that the kit comprises more than one blister card.

The Supreme Court has held that while the "teaching, suggestion, motivation" approach is a valid form of analysis under Graham v. Deere, it is not the only one. See KSR v. Teleflex, 82 USPQ2d 1385 (U.S. 2007) at page 1397 where Justice Kennedy, speaking for a unanimous court, states:

The same constricted analysis led the Court of Appeals to conclude, in error, that a patent claim cannot be proved obvious merely by showing that the combination of elements was "obvious to try."... When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under §103.

It would have been obvious to one of ordinary skill in the art to have arranged the pharmaceuticals and nutrients horizontally or vertically motivated by the desire to arrange the components in a pattern that promotes dosing in a particular order. Since there are only a finite number of ways to arrange the pharmaceuticals and nutrients in the blister packs such as horizontally, vertically and in a circular pattern, it would have been obvious to arrange the components horizontally or vertically[1].

Claims 1-23 are rejected.

Claim 24 is withdrawn.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone

[1] In any case, a claimed device is not patentably distinct from the prior art if the claimed device would not perform differently than the prior art device. In Gardner v. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984).

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lezah Roberts
Patent Examiner
Art Unit 1614

Frederick Krass
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